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SpirHOMEter User manual, III Edition
September 2003

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COSMED Srl - Italy

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Getting started

Important notices

Intended use

SpirHOMEter is an electrical medical device designed to perform pulmonary function tests. It is to be used by physicians or by trained personnel on a physician responsibility.

Caution: Federal law restricts this device to sale by or on the order of a physician.

This equipment has been conceived with the aim of providing an auxiliary instrument allowing:

- the formulation of lung pathology diagnosis;
- important studies concerning human physiology;
- the collection of important information in sport medicine.

No responsibility attaches COSMED Srl for any accident happened after a wrong use of the device, such as:

- use by non qualified people;
- non respect of the device intended use;
- non respect of the hereunder reported precautions and instructions.

Warnings

The device, the program algorithms and the presentation of measured data have been developed according to the specifications of ATS (American Thoracic Society) and ERS (European Respiratory Society). Other international references have been followed when these were not available. All bibliography references are reported in Appendix.

The present handbook has been developed with respect of the European Medical Device Directive requirements which sort SpirHOMEter within Class II a.

It is recommended to read carefully the following precautions before putting the device into operation.

The precautions reported below are of fundamental importance to assure the safety of all COSMED equipment users.

1. This user manual is to be considered as a part of the medical device and should always be kept on hand.
2. Safety, measure accuracy and precision can be assured only:

- using the accessories described in the manual or given with the device. Actually non recommended accessories can affect safety unfavourable. Before using non recommended accessories it is necessary to get in touch with the manufacturer;
- ordinary equipment maintenance, inspections, disinfection and cleaning are performed in the way and with the frequency described;
- any modification or fixing is carried out by qualified personnel;
- the environmental conditions and the electrical plants where the device operates are in compliance with the specifications of the manual and the present regulations concerning electrical plants. In particular grounding reliability and leakage current suppression can only be assured when the device three – wire receptacle is connected to a yellow - green return connected to earth ground. Attempting to defeat the proper connection of the ground wire is dangerous for users and equipment.

3. Before powering the system, check the power cables and the plugs. Damaged electrical parts must be replaced immediately by authorised personnel.
4. Cleaning residue, particulates, and other contaminates (including pieces of torn or broken components) in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminates can potentially be life-threatening. You must follow all the cleaning procedures in System Maintenance, and you must thoroughly inspect the components after cleaning and before each patient test.
5. This device is not suitable for use in presence of flammable anaesthetics. It is not an AP nor an APG device (according to the EN 60 601-1 definitions).
6. Keep the device away from heat and flame source, flammable or inflammable liquids or gases and explosive atmospheres.
7. In accordance with their intended use SpirHOMEter is not to be handled together with other medical devices unless it is clearly declared by the manufacturer itself.

8. It is recommended to use a computer with electromagnetic compatibility CE marking and with low radiation emission displays.
9. It is necessary to make the PC, connected to the SpirHOMEter, compliant with EN 60601-1 by means of an isolation transformer.
10. Graphical symbols used in accordance to present specifications are described here below:

Equipment type B (EN60601-1)

Danger: high temperature

OFF

ON

Protective earth ground

Alternating current

Contraindication

The physical strain to execute the respiratory manoeuvre is contraindicated in case of some symptoms or pathology. The following list is not complete and must be considered as a piece of mere information.

Absolute contraindications

- Post-operating state from thoracic surgery
- Severe instability of the airways (such as a destructive bronchial emphysema)
- Bronchial non-specific marked hypersensitivity
- Serious problems for the gas exchange (total or partial respiratory insufficiency)

Relative contraindications

- spontaneous post-pneumothorax state
- arterial-venous aneurysm
- strong arterial hypertension
- pregnancy with complications at the 3rd month.

Environmental condition of use

COSMED units have been conceived for operating in medically utilised rooms without potential explosion hazards.

The units should not be installed in vicinity of x-ray equipment, motors or transformers with high installed power rating since electric or magnetic interferences may falsify the result of measurements or make them impossible. Due to this the vicinity of power lines is to be avoided as well.

Cosmed equipment are not AP not APG devices (according to EN 60601-1): they are not suitable for use in presence of flammable anaesthetic mixtures with air, oxygen or nitrogen protoxide.

If not otherwise stated in the shipping documents, Cosmed equipment have been conceived for operating under normal environmental temperatures and conditions [IEC 601-1(1988)/EN 60 601-1 (1990)].

- Temperature range 10°C (50°F) and 40°C (104°F).
- Relative humidity range 20% to 80%
- Atmospheric Pressure range 700 to 1060 mBar
- Avoid to use it in presence of noxious fumes or dusty environment and near heat sources.
- Do not place near heat sources.
- Cardiopulmonary resuscitation emergency equipment accessible.
- Adequate floor space to assure access to the patient during exercise testing.
- Adequate ventilation in the room.

Notice: *if accidentally droppings, exposure to heat source and excessive humidity may compromise the validity of the system, we recommend you a check or ask for a technical assistance.*

Safety and conformity

Safety

IEC 601-1 (1988) /EN 60 601-1 (1990);

Find reported below the complete classification of the device:

- Electrical internally powered equipment type B
- Protection against water penetration: IP00, ordinary equipment unprotected against water penetration
- Non sterile device
- Device not suitable in the presence of flammable anaesthetics;
- Continuous functioning equipment;

EMC

SpirHOMEter meets the EMC Directive 89/336

EN 60601-1-2

EN 55011 Class B (emission), IEC 1000-4-2, IEC 1000-4-3, IEC 1000-4-4

Quality Assurance

UNI ISO 9001 (Registration n° 387 Cermet)

Medical Device Directive (CE mark)

MDD 93/42/EEC (Notified Body 0476).

Class IIa

Keynotes

Here are the keynotes used to make the manual easier to read.

Typographic keynotes

These are the typographic keynotes used in the manual.

Style	Description
Bold	indicates a control or a key to be pressed.
"*Italic*"	indicates a messages shown by the firmware.

Graphic keynotes

These are the graphic keynotes used in the manual.

Illustration	Description
	shows the button to click in the software to activate the related feature.

Before starting

Before operating the SpirHOMeter we strongly recommend to check the equipment and register you as a customer.

Checking the packing contents

SpirHOMEter and its software are in two different packaging, because it is necessary only one software to manage more units.

The first purchase will be of two packages:one containing the software, the other one the SpirHOMEter. Make sure that the packing boxes contain the items listed below. In case of missing or damaged parts, please contact your nearest COSMED technical assistance.

SpirHOMEter standard packaging

Code	Qty	Description
C00486-01-05	1	SpirHOMEter unit
C00033-01-05	1	Turbine
A 662 100 001	1	Nose clips
C00063-01-20	2	Conic mouthpiece
C00066-01-10	1	Carrying case
A 410 110 001	4	AAA battery 1,5 V
C00067-02-94	1	Registration card
C01999-02-DC	1	Conformity declaration
C00065-02-91	1	Patient manual

Kit software SpirHOMEter standard packaging

Code	Qty	Description
C02053-02-35	1	PC software
C00021-01-30	1	9 pin F adaptor
C00674-01-12	1	Interface cable RS232
C00067-02-94	1	Registration card
C02046-02-91	1	User manual

Warranty registration

Before using the system, please take a moment to fill in the registration form and the warranty and return them to COSMED, by doing this you are eligible to the customers assistance service.

For further information, please refer to the enclosed registration and warranty form. If the form is not enclosed in the packaging, please contact directly COSMED.

Register the product via software

Together with the PC software, a registration software is supplied. With this software it is possible to fill in an electronic form with the customer information.

1. To run the software, double click on the icon **Registration** or select **Registration…** from **?** menu.
2. Type the requested information and click **Send…** to send the form via e-mail to COSMED.

How to contact COSMED

For any information you may need, please contact the manufacturer directly at the following address:

COSMED S.r.l.
Via dei Piani di Monte Savello, 37
P.O. Box n. 3
00040 - Pavona di Albano
Rome - ITALY

Voice: +39 (06) 931.5492
Fax: +39 (06) 931.4580
email: **customersupport@cosmed.it**
Internet: **http: //www.cosmed.it**

Complain, feedback and suggestions

If you have any complain, feedback information or suggestion, please inform us at **complain@cosmed.it.**

PC configuration required

- Pentium 133 MHz.
- Windows 95, 98, XP.
- 16 Mb RAM .
- 3.5 drive.
- VGA, SVGA monitor.
- Serial Port RS 232 available.
- Any Mouse and Printer compatible with the MS Windows™ operative system.
- PC conform to European Directive 89/336 EMC

Technical features

Flowmeter	Bidirectional digital turbine
Flow Range:	0.03 - 20 l/s
Volume Range:	12 l
Accuracy:	± 3% or 50 ml
Resistance @12 l/s:	< 0.7 cmH2O/l/sec
Memory:	120 tests
Display:	LCD 2 lines x 16 char
Keyboard:	4 multi-function keys
Serial port:	RS232C
Power supply:	4 AAA 1,5V batteries
Dimensions:	175 x 35 x 35 mm
Weight:	120g

Measurements

Measured parameters

Symbol	UM	Parameter
FVC	l	Forced Expiratory Vital Capacity
FEV1	l	Forced Expiratory Volume in 1 sec
FEV1/FVC%	%	FEV1 as a percentage of FVC
PEF	l/sec	Peak Expiratory Flow
FEV0.5	l	Forced Expiratory Volume in 0.5 sec
FEV6	l	Forced Expiratory Volume in 6 sec
FEV1/FEV6	%	FEV1 as a percentage of FEV6
FEV6/FVC%	%	FEV6 as a percentage of FVC
Best FVC	l	Best Forced Expiratory Vital Capacity
Best FEV1	l	Best Forced Expiratory Volume in 1 sec
Best PEF	l/sec	Best Peak Expiratory Flow
Vmax25%	l/sec	Expiratory Flow @25% of the FVC
Vmax50%	l/sec	Expiratory Flow @50% of the FVC
Vmax75%	l/sec	Expiratory Flow @75% of the FVC
FEF25-75%	l/sec	Mid-exp flow between 25-75%FVC
FET100%	sec	Forced expiratory time
FEV2	l	Forced Expiratory Volume in 2 sec
FEV3	l	Forced Expiratory Volume in 3 sec
FEV2/FVC%	%	FEV2 as a percentage of FVC
FEV3/FVC%	%	FEV3 as a percentage of FVC
FEV1/VC%	%	Tiffenau index
FEF50-75%	l/sec	Mid-exp flow between 50-75%FVC
FEF75-85%	l/sec	Mid-exp flow between 75-85%FVC
FEF0.2-1.2%	l/sec	Mid-exp flow between 0.2 l - 1.2 l
FiVC	L	Inspiratory Forced Vital Capacity
FiF25-75%	l/sec	Forced mid-inspiratory flow
FiV1	l/sec	Forced Inspiratory Volume in 1 sec
PIF	l/sec	Peak Inspiratory Flow
VEXT	ml	Extrapolated Volume (back extrapolation)
PEFT	msec	Time to PEF (10% - 90%)

Installation

Prepare the SpirHOMEter

Install/replace batteries

The devices is battery operating. It uses 4 manganese alkaline AAA-size 1,5V batteries.

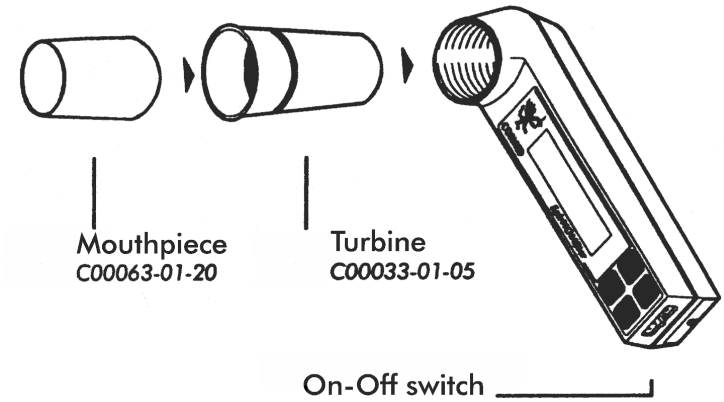
1. The on/off switch must be set to **0**.
2. Remove the battery compartment cover.
3. Insert the batteries as indicated on the back side of the device.
4. Close the battery compartment.

It is suggested to replace the batteries only if you have the new ones. The SpirHOMEter, without batteries, retains the stored data only few minutes.

***Note**: If you don't use the SpirHOMEter for a long time, remove the batteries, being careful to save on the PC the tests in the unit memory.*

Install the turbine

Remove the transparent wrapping and insert the turbine as shown in the following figure. Be sure to push the turbine up to touch the end of the holder.



Turn on the device

Set the on/off switch to **I.**

Note: *If the switch is already set to* ***I****, but the display doesn't show anything, turn off and then turn on the device. The SpirHOMEter, if not used, turn off itself automatically after about one minute.*

Set-up the SpirHOMEter

The SpirHOMEter has controls for data transmission, archive deletion, setting date and time. In order to use these controls, you have to access a menu that, from now on, will be called *Control menu*.

The keyboard

The keyboard is made of the following keys:

Deletion

Transmission

Calibration

Configuration

For the sake of ease, we shall refer to the SpirHOMEter keys with the numbers they represent on the keyboard: **0**, **1**, **2** and **3** respectively.

Access to Control Menu

1. Hold the key **3** down and, at the same time, switch on the device by setting the on-off switch to **I**.
2. Release the key **3**, and the display panel will display a menu, different from that accessible by the patient.

```
2.Calib 3.Config
1.Trans 0.Cancel
```

By pressing the respective keys it is possible to:

0 delete all the data stored in the memory

1 transmit stored data to the PC via RS-232 or via modem

2 calibrate the flowmeter

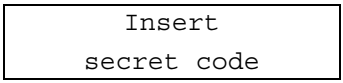
3 adjust the internal clock, configure the modem option and set up the patient data.

Let us exhamine these functions in detail.

Delete stored data

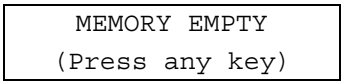
Before the SpirHOMEter is delivered to the patient, it must be reprogrammed to free up the memory, used during the last session.

1. Access the control menu
2. Press the key **0** (deletion). The following message will appear:



3. Press in succession the keys **3**, **1**, **0**, **2**.

At the end of this operation, the following message will appear on the display of the device:



Transmit data to the PC

This function is described in the chapter *Database management*.

Calibrate the flowmeter

This function is described in the chapter *Calibration*.

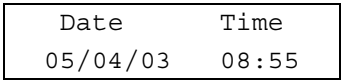
Set-up date and time

In order to set up the date and the time:

1 Access the control menu

2 Press the key **3** to enter in *configuration*

3 Press the key **3** (date).



4 Move into the fields dd/mm/aa – hh/mm, by means of the key **3**

5 Modify the time and/or the date with the key **2** (forward) or **1** (backward)

6 Confirm with the key **0**.

Modem option

With this option, the patient can send his/her tests via modem, directly from his/her own home.

To configure the modem option (to store the phone number to be called):

1 Access the control menu

2 Press the key **3** to enter in *configuration*

3 Press the key **1** (modem).

4 To configure the transmission type (tone or pulse), press the key **1** (the setting switches between tone and pulse, the selected setting is the one in capital letters).

5 To set up the telephone number, press the key **2** and then modify the ciphers by means of the keys **2** (increase) and **1** (decrease), moving by means of the key **3**.

6 At the end of the entry, set up the character #

7 Confirm with the key **0**.

Set-up patient data

This function allows the user to set up the ID code and the best PEF of the patient.

It is very important setting-up correctly the ID code of the patient: this code is used to refer the test data, transmitted to the PC through serial or modem connection, to the proper patient card.

To set-up the patient data:

1 Access the control menu

2 Press the key **3** to enter in *configuration*

3 Press the key **2** (paziente).

4 To set up the best PEF press the key **1**. To decrease or increase the displayed value, press respectively the key **1** or **2**. Confirm with the key **0**.

5 To set up the ID code of the patient, press the key **2** and then modify the ciphers by means of the keys **2** (increase) or **1** (decrease), moving by means of the key **3**. Confirm with the key **0**.

Set-up the device

When the SpirHOMEter is left without power for a relatively long period of time, when turned on it displays the following message:

```
Setup
the memory...
```

Note: *When this message appears, any data stored in the device are lost. Delete the stored data as already described.*

Software installation

Installing the software

1. Select **Run...** from Windows **Start** menu.
2. In the Command line box, type **a:\install** (assuming the disk is in drive A:).
3. Click on **OK** (or press **ENTER** key).
4. The program will load up a dialog box and ask for a directory where to be installed.
5. When the installation is over, the program will advise you with a message indicating that the installation has been successfully completed, click on **End.**

***Notice**: The software is copy-protected. Install the software from the original disk.*

Run the software

1. In the Windows **Start** menu, open the Program Group in which the software was installed.
2. Click the **SpirHOMEter** icon.

PC port configuration

The first time the software is used, it is necessary to configure the communication port with the PC (USB, COM1, COM2,…).

For further details, see the chapter *Database management*.

Software main features

Display

The program may contain several windows. The active window is highlighted with a different colour of the caption. Some functions of the program are "active window" sensitive (Print, right key of the mouse).

Tool bar

Many of the functions that may be selected from the menu can be activated more rapidly by clicking with the mouse on the corresponding icon in the tool bar.

Positioning the mouse cursor on one of the buttons of the toolbar (if the option Hints is enabled), the description of the corresponding function is shown in a label.

Show/hide the toolbar

Select **Toolbar** from **Options** menu in order to show or hide the toolbar.

Dialog windows

The typical operating environment of Microsoft Windows is the Dialog box. This window is provided with a series of fields in which input the information.

Use of the keyboard

- To move the cursor among fields, press the **Tab** key until you reach the desired field.
- Press the **Enter** key to confirm the information input on the dialog box or press the **Esc** key to cancel changes.

Use of the mouse

- To move the cursor among fields, move the mouse on the desired field and left-click.
- Click on the **OK** button with the Left button of the mouse to confirm the information input on the dialog box or click on **Cancel** button to cancel changes.

Scroll bars

Some windows are provided with scroll bars that help to see data exceeding the window space available.

- To move the scroll bar row by row click the scroll arrows at the end of the scroll bars
- To move the scroll bar page by page click on the grey area at both sides of the scroll fields

On-line help

COSMED Help is a complete on-line reference tool that you can use at any time. Help is especially useful when you need information quickly or when the user manual is not available. Help contains a description of each command and dialog box, and explains many procedures for accomplishing common tasks.

To get the Help on line, press the **F1** key.

Software version

To know the software version and the serial number of the software, select **About SpirHOMEter…** from **Help** menu.

Calibration

Turbine calibration

The SpirHOMEter is calibrated by COSMED. ATS recommends a daily calibration of the turbine. However if it is correctly maintained, turbine retains its precision for longer periods. We advice to calibrate the turbine daily to detect malfunctioning.

The check must be carried out measuring a known volume (calibration syringe) carrying out a FVC test, and verifying the measured value. If the difference between the predicted (real) and the measured value is greater than 3%, it is necessary to carry out the calibration procedure.

In order to calibrate the turbine:

1. Access the control menu.
2. Press the key **2**. The following message will appear.

```
2.New       K=128
1.Standard  0.Esc
```

3. To cancel the operation, press the key **0**.
4. To restore the factory settings, press the key **1**.
5. To carry out a new calibration, connect the calibration syringe to the turbine and press the key **2**.
6. Perform 2 or 3 complete inspirations/expirations and wait for a message similar to the following one:

```
Pred  Meas %Corr
3.00  3.32  -9.7
```

   Pred represents the real syringe volume, *Meas* the measured volume, *%Corr* the applied correction (in percent).

7. Press a key. The following message will be displayed:

```
 2.Cancel   New
1.Store   K=089
```

   K indicates the new calibration factor.

8. Press the key **1** if you want to store the new calibration factor, otherwise **2** to cancel the operation.

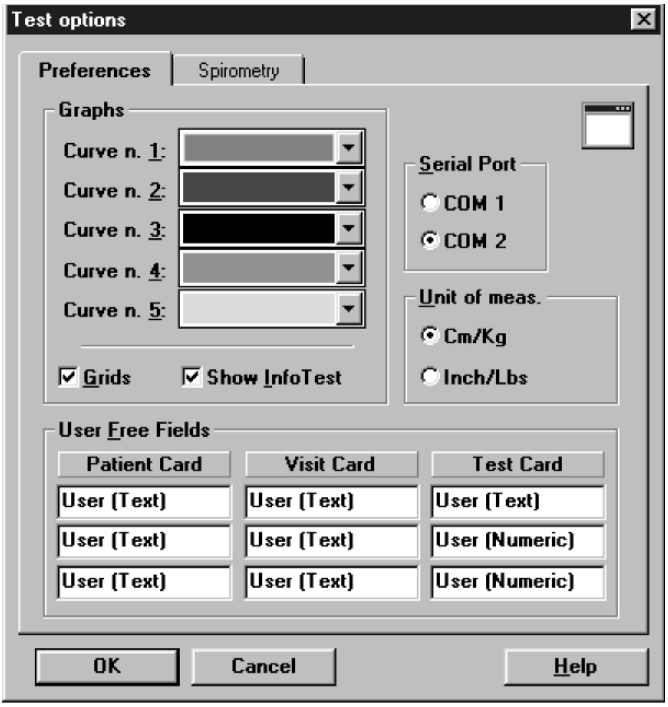
The 3-liters calibration syringe can be purchased directly from COSMED (P/N C00243-01-06).

Note: *If a bacterial filter is used for the tests, do use it also during the turbine calibration.*

Database Management

Settings

The software allows to configure some options selecting **Configure** from the **Option** menu.



Graphs

All the graphs visualised and/or printed can be customised in colours and appearance.

1. Select the desired colours of the curves (5 curves max can be overlapped on the same graph).
2. Enable or disable the **Grid** option.
3. Enable or disable the **Show Info Test** option.

Serial port

You must select the serial port RS 232 that will be used to connect the SpirHOMEter with the PC.

To select the serial port, click on the proper **COM** button (the selected port must be different from the mouse one).

Units of measurements

It is possible to configure the units of measurements, weight and height, for printing and viewing.

To select the units of measurement click on **cm/Kg** or **in/lb** according to the desired format.

Using extra fields

The Patient's database is organised in 3 different cards (Patient card, Visit Card and Test card.) where it is possible to store the information about patients and visits.

Besides the standard information, it is possible to customise some fields (user free fields), entering and labelling measurements coming from other devices.

The customisable free fields are:

- 3 fields in the Patient Card (Patient's information)
- 3 fields in the Visit Card (information about the visits)
- 3 fields (2 numeric) in the Test card information about Test)

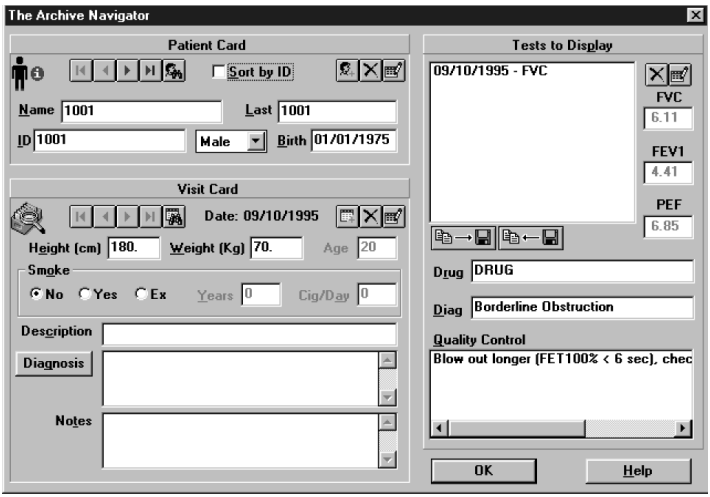
Customise the fields

In the group **User free fields** type the desired text in the 9 fields available.

Patient's database

The Patients database consists of a Patient Card, a Visit Card and a Test Card in which are listed all tests performed by the patient.

Select **Archive Navigator** from the **File** menu or press the button by side.



▲▲▲

***Note**: after having deleted a record (patient, visit or test), it is recommended to reorganize the archive in order to free disk space.*

Patient Card

It collects all the information of a patient (first name, last name, date of birth) which remain the same for each visit. For each patient there is only one Patient Card, which is created the first time the Patient performs a test.

To move within the database use the following buttons:

Move to the first patient in the archive

Move to the previous patient in the archive

Move to the next patient in the archive

Move to the last patient in the archive

Find a patient in the archive

Enter a new patient in the archive

Delete current patient from the archive

Edit the current patient card

Visit Card

It collects all information relative to the visit (diagnosis, visit description...) and to the patient information subject to change between one visit and another (height, weight, smoke). Each patient can be related to several Visit Cards provided they have been created in different days. Before carrying out any spirometric test it is necessary to create a new Visit Card or to open the today's Visit Card.

To move within the database use the following buttons:

Move to the first visit in the archive

Move to the previous visit in the archive

Move to the next visit in the archive

Move to the last visit in the archive

Find a visit in the archive

Enter a new visit card in the archive

Delete current visit card from the archive

Edit the current visit card

Test Card

It contains all the information about the test.

To move within the database use the following buttons:

Delete current test from the archive.

Edit the current test

Import/export a Tests card

This function allows to import /export a test card with the respective visit and patient card.

1. Select the patient.

2. Choose the tests to be exported and press the key by side. All data will be imported/exported in the XPO file format (Cosmed proprietary).

Diagnosis Database

The program allows to manage a diagnosis database, whose records are composed by a diagnosis ID code and a string of text.

The report of the visits can be done either by typing the desired text in the field “Diagnosis” of the Visit Card or, more quickly, retrieving from the diagnosis database the desired one.

If you want to insert, modify or delete a diagnosis from the database select **Database Diagnosis...** from the **File** menu.

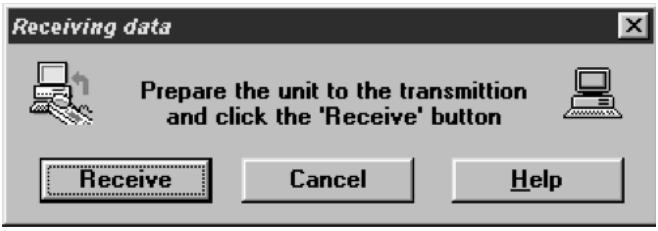
Transmit data to the PC

Before starting any analysis you must upload the data from the spirometer via the serial port. This operation is made up of the two following steps:

1. Transmit data
2. Link the test to a patient in the archive

Transmit data

1. Link up the spirometer to the PC with the **RS232** cable supplied.
2. Select **Receive** from the **Test** menu



3. Access the control menu
4. Press the key **1** to enter data transmission.
5. Press another time the key **1** to select the transmission towards PC.
6. Confirm pressing the **Receive** button on PC.
7. Start data transmission from the spirometer by pressing any key.

A solid bar on the PC display will highlight the state of data acquisition from the SpirHOMEter.

Note: *Be sure that the program is correctly configured to acquire data through the serial port (COM1 or COM2) as previously described.*

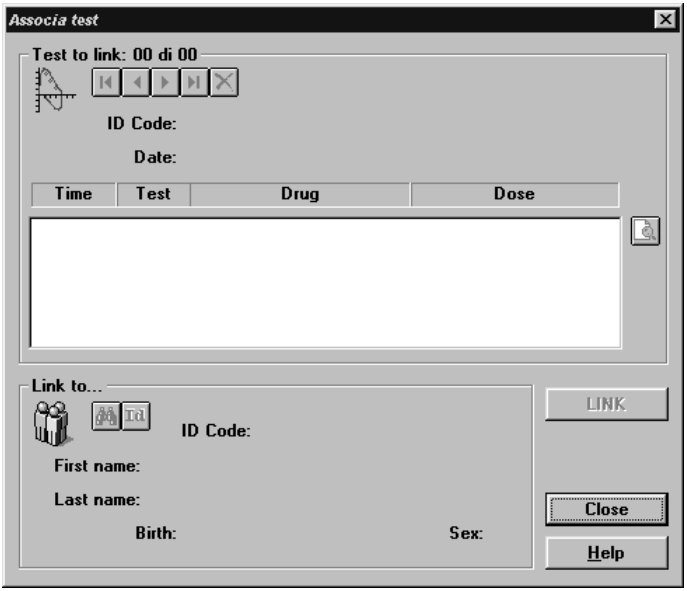
At the end of the data transmission, if reception has taken place correctly, the program will open a window to link the tests to the patient (see later). The SpirHOMEter display will show the following message:

```
Check  the
data rec'd
```

Link the test to a patient in the archive

The data received from the spirometer are held in temporary memory. These tests must then be stored within the patient database by linking each test to the corresponding patient.

1. Select **Link** from the **Test** menu.



2. Select the test you want to link in the top area of the window.

Move to the first test to link

Move to the previous test to link

Move to the next test to link

Move to the last test to link

Delete current test

View a preview of the report

3. Select the correspondent Patient in the bottom area of the window.

Find a patient in the archive by the Archive Navigator

Id Find a patient in the archive with the same ID Code of the current test to link.

Link Link the current test to the current patient.

Archive maintenance

The software allows to manage files selecting **Archive** from the **File** menu.

It is advisable to perform the archive reorganisation every month, in order to free space on the hard disk and/or to correct possible errors present within the database.

It is possible also that your have no more hard disk space. So, you have to delete all the data. In this case, it is useful to perform the initialising.

Reorganise the archive

1. Select **Reorganize archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

Delete the archive

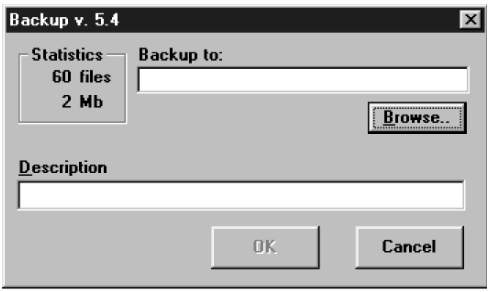
1. Select **Initialize Archive** from the **File** menu.
2. Wait for the end of the operation before performing any other function.

Backup and restore

It is strongly recommended to backup files, a warning message will be displayed monthly. This function allows the user to restore the data if the PC or the HD will not work anymore.

Backup

1. Select **Backup archive** from the **File** menu.

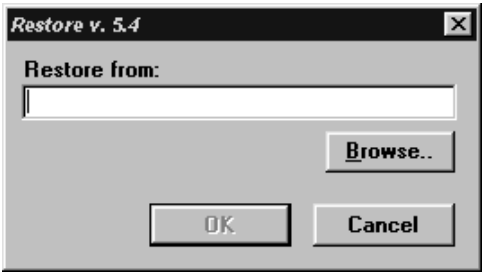


2. Selecting the destination path with the **Browse** key or press **New** to create a new directory. Press **OK** to confirm.

3. In the dialog box it will appear an estimate of the number of floppy you need in order to back up the archives. Press **OK**.

Restore

1. Select **Restore archive** from the **File** menu.



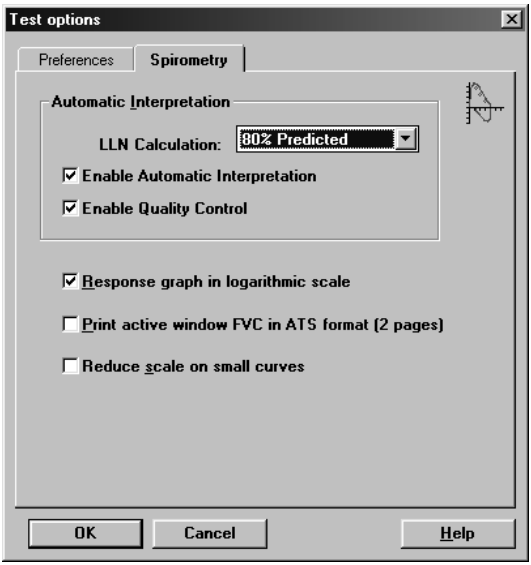
2. On the **Restore** dialog box specify the drive source and press **OK**, a dialog box will appear indicating all data of the backup processed.

Spirometry

Setting spirometry options

The software allows to configure some options selecting **Configure** from the **Option** menu.

Spirometry



Automatic Interpretation

The SpirHOMEter has the function of interpreting each test performed by a patient visualising an automatic diagnosis. The algorithm has been calculated basing on "Lung Function Testing: selection of reference values and interpretative strategies, A.R.R.D. 144/ 1991:1202-1218". The automatic diagnosis is calculated at the end of the FVC if:

- the automatic diagnosis option is enabled.
- the patient's anthropometric data allow the calculation of the LLN (Lower Limit of Normal range).
- at least one FVC test has been performed.

To enable/disable the automatic diagnosis:

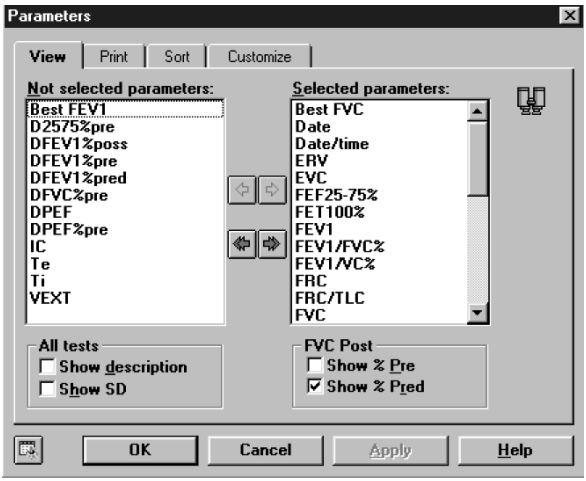
1. Click on **Enable Automatic Interpretation**.
2. Select the LLN (Lower Limit of Normal Range) criteria among the ATS (LLN=Pred-0.674*SD), ERS (LLN=Pred-1.647*SD) or 80%Pred (LLN=Pred*0.8) specifications.

Quality control

The SpirHOMEter allows a quality test control. The calculation has been carried out referring to "Spirometry in the Lung Health Study: Methods and Quality Control, A.R.R.D. 1991; 143:1215-1223". The messages concerning the quality control are shown at the end of the test.

To enable/disable the quality control, click on **Enable Quality Control** checkbox.

Parameters manager



The program allows to calculate a huge number of parameters; it is advisable, in order to simplify the analysis of the results, to view, to print and to sort the desired parameters only. Select the menu item **Options/Parameters...**

View

Move the parameters to view into the *Selected parameters* list.

Print

Move the parameters to print into the *Selected parameters* list.

Sort

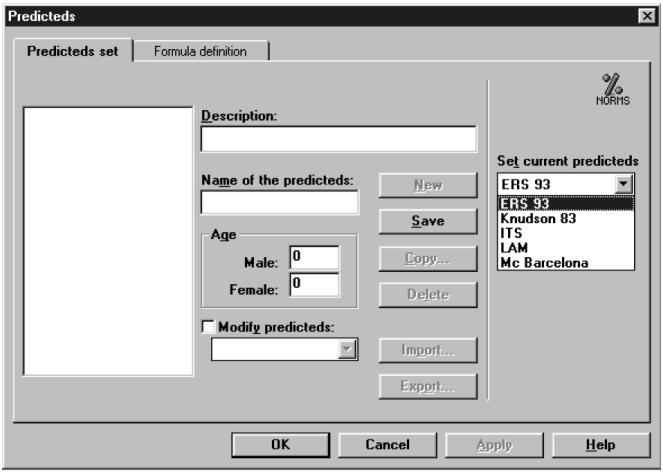
Drag the parameter up or down with the mouse.

Customise

Add, modify and delete custom parameters.

If it is necessary to restore the default parameters press the button in the left corner of the window to initialise the parameters database.

Predicted values manager



The program contains a preset of predicted equations, but the user is allowed to customise its own predicted sets. Select **Predicteds.**.. from **Options menu.**

The window is divided into two forms: **Predicteds set** and **Formula definition**.

Predicteds set

This form allows the user to manage the set of predicteds. The following information define a set:

Name: identifies the set and cannot be duplicated;

Description: free field;

Age: the adult predicteds start since this age.

To enter a new set of predicteds click on the **New** button. The field **Name** must be filled and must be unique. To stop without saving click on the **Cancel** button. To save the set, click on the **Save** button.

To delete a set of predicteds click on the **Delete** button. If a set is deleted, also the associated formulae are deleted.

It is possible to generate a new set of predicteds with the same attributes and the same formulae of the selected one. To do this click on the **Copy**... button and specify a new Name.

To import a set of predicteds click on the **Import**... button and select a file of Predicteds files type.

To export a set of predicteds click on the **Export**... button.

In the list **Set current predicteds** choose the current predicteds for printing and viewing.

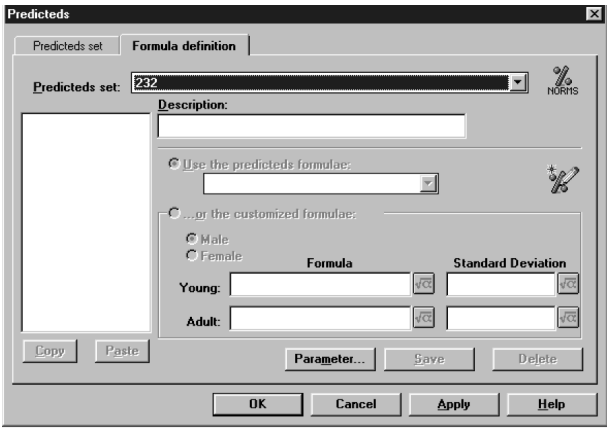
Set the current predicted

The SpirHOMEter allows to calculate the predicted values according to the following configurable sets:

Adults	Paediatrics
ERS 93	Zapletal
Knudson83	Knudson83
ITS white	ITS white
ITS black	ITS black
LAM	LAM
MC Barcelona	MC Barcelona
Nhanes III	Nhanes III

Select the desired choice in the group **Predicted**.

Formula definition



This form allows the user to manage the formulae associated to a set of predicteds.

Select the set of predicteds from the list **Predicteds** set.

To insert a new parameter click on the **New**... button.

The parameter formulae can be:

- calculated according to the predicteds in the list **Use the predicteds formulae**;

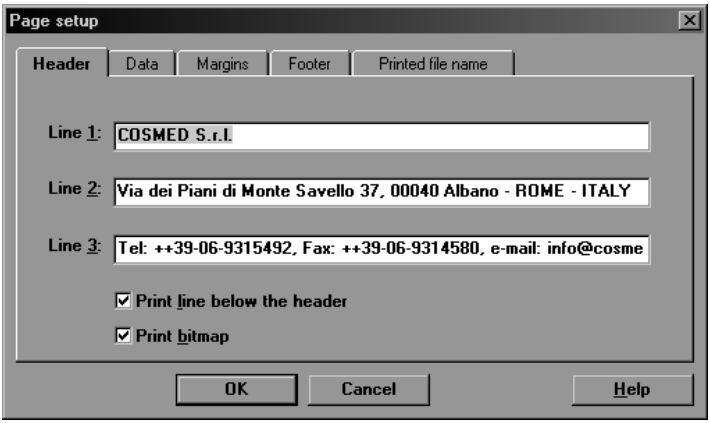
- customised by the user with the option **...or the customised formulae**.

The **Delete** button deletes the selected parameter.

The **Copy** button stores the selected parameter in memory.

The **Paste** button inserts a new parameter from the one copied. If the name is not unique, the user is asked whether to specify a new name or to replace the existing parameter.

Page set-up



Select **Page Setup**... from the **File** menu.

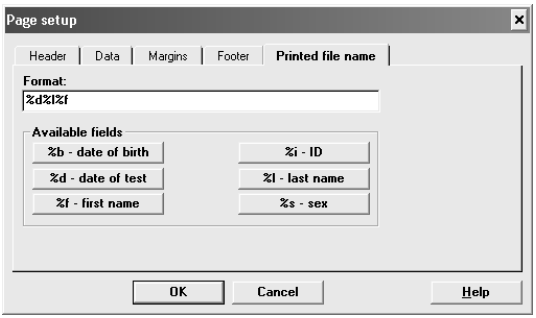
Header — All the printouts carried out by the program are preceded by 3 rows of customisable header (usually they contain the name and the address of the Hospital using the spirometer).

Data — Patient and visit information are printed below the header. These data are reported on 3 columns and 5 rows. the user may configure the disposition, change and eventually cancel the fields, as he prefers.

Margins — Configures the print margins from the borders of the paper. The unit of measure is decided in **Units of measurements**.

Footer — Configures information at the bottom of the page.

Printed file name Defines the automatic name to be asssigned to the pdf file, if the report will be printed in this format.



In the example it has been set to create a filename composed by <date of the test> followed by <last name> and <first name>.

Spirometry tests

Tips for correct use of the device

▲▲▲
***Note**: Read carefully the contraindications in Chapter 1.*

Before the SpirHOMEter is delivered to the patient, we would advise that he/she receive a short course in use of the instrument and correct performance of the FVC test.

In order to reach a clearer diagnosis and/or check the effectiveness of the treatment being administered, it is always advisable to record the severity of the symptom before the test, by pressing the reative keys

Keyboard

For the sake of ease, we shall refer to the SpirHOMEter keys with the numbers they represent on the keyboard:

Key **0**.

Key **1**.

Key **2**.

Key **3**.

Drugs

In order to analyze the state of the lung function also as a function of the treatment being received, it is possible to record the time at which the drug is taken. The SpirHOMEter records the date and the time at which one or more drugs (up to a maximum of 4) are taken.

After switching on, the date and the time appear on the display panel, followed by this message:

```
Do you want to
enter drugs ?
```

Press **0** for NO, press **1**, **2** or **3** for YES.

If YES, the device scrolls through the list of drugs to be taken.

```
Drug A?
```

Press **0** to indicate that the drug was not taken, otherwise press **1**, **2** or **3** to confirm.

When the stage has been completed, the following message is displayed:

```
Carry out
test ?
```

Press **0** to terminate the session, press **1**, **2** or **3** to perform the test.

Recording the severity of symptoms

If the previous question has been answered affirmatively, the list of symptoms appears. The first is COUGH

```
Cough ?
```

Give the severity of the symptom (which will be recorded) by pressing **0** (absent), **1** (slight), **2** (medium), **3** (severe).

Immediately after this, the symptoms DYSPNEA, MUCUS and WHEEZING will appear in order. Repeat the operations described for COUGH.

When this phase has been completed, the following message will appears:

```
Carry out
test no.1
```

Performing the test

The Forced Vital Capacity (FVC) test can also be performed by taking a few normal breaths before step 4 (breathing in fully).

For hygienic reasons, we strongly recommend the use of a bacterial filter.

1. Fit the mouthpiece or the bacterial filter to the device
2. Apply the noseclip
3. Take the mouthpiece tightly between lips and breathe normally
4. Breathe in fully
5. Breathe out as quickly and long as possible
6. At the end of the test some of the values obtained will appear on the display.

When the first test is complete, carry out the second, and then a third if the device requires it.

Note: *If the tests are not carried out correctly, the following error message will appear, and in this case the test session must be repeated.*

```
Test finished
incorrectly
```

Viewing results

All the visualisation functions refer to the test carried out by the Current Patient, whose name is indicated on the left-side of the status bar.

To view tests results:

1. Select the **Patients** from the **File** menu
2. Select the patient corresponding to the test you want to view.
3. Select in the list box of the tests up to 5 tests of the kind (FVC, VC/IVC, or MVV) and press **OK**.

To switch between graph and or data use the following buttons on the toolbar:

view Flow Volume graph (F5)

view Volume Time graph (F6)

view data of the test (F7)

If you need more than one visualisation meantime use the **New Window** function from the **Window** menu.

If you need to display a list of visits:

- Select **Visits list...** from the **File** menu.
- Type the name of the Company and/or the time interval desired or simply confirm for the complete list.

Tests of the current patient

If a **current patient** has been selected you can quickly view his tests selecting **Test current patient...** from the **View** menu.

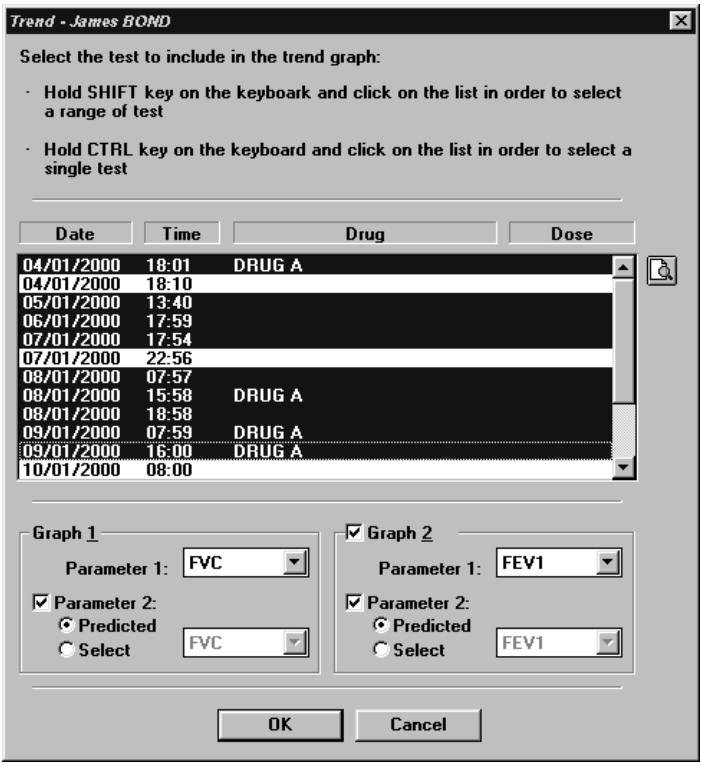
Delete a test

1. Select **Patients** from the **File** menu or press the button by side.
2. Select the test that you want to eliminate from the list of the tests referred to the Current Patient and press **Delete**.

View a trend

It is possible to analize the trend of measured parameters (FVC, FEV1, etc.) graphing the values, with reference to the symptoms and to the drugs taken.

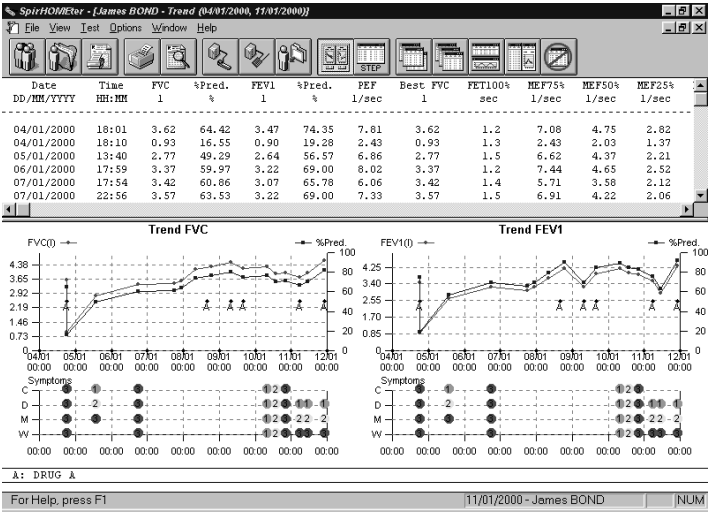
1. Select **Trend...** from **View** menu.
2. It will be open a window in which are displayed all the tests linked to the current patient.Select the test you want view the trend, following the instructions on the window.



3. In the lower part of the window, select the parameters to graph. For each trend graph, you can choose if it will be graphed a measured parameter and its predicted value or two different measured parameters.
4. Press **OK** to confirm.

A window will appear, divided into two sections: in the upper section you can see the measured parameters of all the tests, in the lower part, the trend graphs. On the graphs will be pointed

out when the patient had taken the drugs; below the graphs, for each time, it is shown the severity of the symptoms.



You can choose to view, in the lower part of the window, the trend graphs or the measured values, from the **View** menu.

Printing results

You can print out in three different ways:

- printing the Report
- printing the Active Window

Printing Reports

To print a report of the current visit, select **Print report…** from **File** menu. In the dialog box, select the visit you want to print the report.

The software will choose automatically the best performed test (if more than 1 test was performed).

- Selecting the option **One page (no ATS)** the report will contain, on one page, the F/V and V/t graphs of the best test, overlapped on the **FVC Post**, the patient data, the notes, the diagnosis and the test results.
- Otherwise the report will contain two pages, the first with the patient data, the graphs and the diagnosis, and the second one with the measured parameters, according to the ATS recommendations.

Select the desired options:

FVC graph	Prints the F/V and V/t curves for the best FVC test.
One page (no ATS)	Prints data and graphs on the first page.
Preview	Views a report preview on the screen.

Printing the active window

This active window printout function is only enabled when the active window (title bar highlighted) is one of the following objects:

- Any kind of Graph.
- Numeric data
- List of visit

To print the active window select **Print Active window** from **File** menu.

Printing a series of reports

Sometimes it is useful to printout automatically a series of reports (all tests carried out with the employees, all tests carried out in the today's session).

To print out proceed as follows:

1. Select **Visit List** from the **File** menu
2. Set the criteria of the visits to be added in the list (from, to,...)
3. Select **Print Report** from the **File** menu.

Electronic reports (*.pdf)

If an Adobe PDF writer "Printer Driver" is installed and set as the default printer, it is possible to store the printout report automatically in any location of the HD or eventually LAN paths according to a customizable filename format.

It is possible to define the created filename format selecting **File/Page Set up...** (see Page set-up).

Export data

With this function you can export the test data in 4 different formats:

- *.txt (ASCII)
- *.xls (Microsoft Excel)
- *.wk1 (Lotus 123)
- *.xpo (Cosmed)

Export a test

1. Select **Export tests** from the **File** menu**.**
2. Select the test to export from the list box and press **OK**.
3. Type the name and the format of the file in the dialog **Save as**. If the ASCII format is selected, the Text button in the dialog box Save as allows you to configure the separators for character based files.

   With the *.xpo Cosmed file format it is possible to import data from another Quark archive. Press **OK** to confirm.
4. Select the folder for the export and type the file name. Press **OK** to confirm. A status bar will show the file creation.

System maintenance

System maintenance

All service operations which are not specified in this user manual should be performed by qualified personnel in accordance with the service handbook (to be required to the manufacturer).

All materials used in the construction of the SpirHOMEter are non toxic and pose no safety risk to the patient or operator.

Prior to the device cleaning, disinfection and inspection it is necessary to switch off the device and to disconnect adapters from the supply mains.

In order to guarantee the highest accuracy of measurements we recommend you to disinfect the turbine periodically.

Cleaning and disinfection

Cleaning and disinfecting instructions are of fundamental importance to control infections and assure patient safety. In fact aspiration of residue, particles and contaminated agents are life – threatening.

In this handbook we strongly recommend you to follow the rules worked out by ATS and ERS (see: "Lung Volume Equipment and Infection Control" – ERS/ATS WORKSHOP REPORT SERIES, European Respiratory Journal 1997; 10: 1928 – 1932), which are summarised and adapted for COSMED products as follows:

- Accessible internal as well as external surfaces of equipment exposed to expired gas should be washed and disinfected prior to testing of subsequent patients.
- Disinfecting should ideally be performed by heat sterilisation, but gas or liquid sterilisation can be used if the equipment is well cleaned first (no droplets of saliva/sputum remain).
- Disposable gloves should be worn when handling mouthpieces, when cleaning equipment exposed to saliva or sputum and especially when drawing blood.
- Laboratory staff should wash hands prior to testing of each patient.
- Adopt particular precautions when testing patients with recognised high – risk communicable diseases (e.g. tuberculosis, multidrug – resistant staphylococcus). In these

cases, the clinical need for such testing should justify the risks.

During the disinfection:

- do not use alcohol or other liquids containing gluteraldehyde on the exterior surfaces of the equipment. Actually they can damage polycarbonates plastics and may produce unhealthy substances.
- do not use abrasive powders or glass cleaners containing alcohol or ammonia on the plexiglas components of the equipment
- do not steam autoclave any parts of the equipment unless it is clearly specified.
- do not immerse the optoelectronic reader.

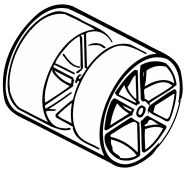
▲▲▲
Warning: *Do not use alcoholic solutions for the turbine, otherwise there can be damages to the plastic material.*

Cleaning the turbine flowmeter

It is necessary to disinfect periodically the turbine for sanitary measures or/and for the correct device function.

As disinfecting solution it is suggested Sodium hypochlorite 5% (bleach).

The disinfecting procedure is easy and may be effected every time the user needs, keeping attention to some precautions:



1. Take out the turbine.
2. Dip it in a disinfectant solution (non alcoholic based) for about 1 hour.
3. Rinse the turbine in a vessel, filled of clean water, shaking gently to remove the disinfectant (do not clean the turbine by putting it under running water!).
4. Let it dry to air.
5. After cleaning the turbine, check if the turbine propeller rotates freely even with a low speed air flow.
6. Connect the turbine to the reader.

Precautions during the cleaning of the turbine

1. Do not expose the turbine to high heat and do not put it under running water.
2. Do not ever dip the optoelectronic reader in any kind of solution, the liquid infiltration would damage the internal circuit.
3. Do not use alcoholic solutions to clean the turbine.

Suggested disinfection solutions

Helipur H Plus	Braun Melsungen AG
Gigasept FF	Schulke & Mayr GmbH
Dismozon pur	Bode Chemie GmbH
TETA-S	Fresenius AG
CIDEX	Johnson & Johnson

Inspections

The equipment requires easy inspections to be carried out in order to assure a proper electrical and mechanical safety level in the years.

These inspections are highly recommended after a rough use of the equipment or after a period of storage in unfavourable environmental conditions.

Referring to the electrical safety, it is important to check the conditions of insulation materials of cables, plugs and any other visible part by means of simple inspection, when the equipment is switched off and disconnected from the supply mains.

Extract the turbine from the unit and verify, by inspection, that the turbine axis fits correctly its seats and the blade is strongly fastened on the axis itself (it can be useful to shake slightly the turbine in order to note any anomalous movement).

Check if there are any torn or broken components in the breathing circuits: remember that they can create safety risk to patients during tests.

Replace the batteries

▲▲▲
Note: *Do not replace the battery if you don't have the new ones ready. If the SpirHOMEter is left without batteries, it retains stored data only for few minutes.*

Replace the batteries when the following message appears:

```
LOW
BATTERIES
```

The SpirHOMEter uses 4 AAA-size 1,5 Volt vatteries.

1. Check that you have the new batteries ready.
2. The on-off switch must be set to **0**.
3. Remove the cover of the battery compartment.
4. Remove the old batteries.
5. Insert the new ones as indicated on the back of the device.
6. Close the battery compartment by sliding the cover along the slots.

Appendix

Service - Warranty

Warranty and limitation of liability

COSMED provides a one (1) year limited warranty from the date of the original sale of COSMED products. All COSMED products are guaranteed to be free from defect upon shipment. COSMED's liability for products covered by this warranty is limited exclusively to replacement, repair, or issuance of a credit for the cost of a defective product, at the sole discretion of COSMED. COSMED shall not be liable under the foregoing warranty unless (i) COSMED is promptly notified in writing by Buyer upon discovery of defect; (ii) the defective product is returned to COSMED, transportation charges prepaid by Buyer, (iii) the defective product is received by COSMED no later than four weeks after the last day of the one (1) year limited warranty period; and (iv) COSMED's examination of the defective product establishes, to COSMED's exclusive satisfaction, that such defect was not caused by misuse, neglect, improper installation, unauthorised repair or alteration, or accident. If the product is manufactured by a third-party, COSMED shall make available for the Buyer's benefit only those warranties which COSMED has received from the third-party manufacturer(s). COSMED hereby specifically disclaims any and all warranties and/or liabilities arising from defect(s) and/or damage(s) to and/or caused by products manufactured by third-party manufacturers. Buyer must obtain written authorisation from COSMED prior to the repair or alteration of COSMED products(s). Failure of Buyer to obtain such written authorisation shall void this warranty.

COSMED hereby specifically disclaims any and all other warranties of any kind, whether express or implied, in fact or by law, including, but without limitation, any and all warranties of merchantability and/or fitness for a particular purpose.

COSMED shall not be liable for special, indirect and/or consequential damages, nor for damages of any kind arising from the use of any COSMED's products, whether said products are used alone or in combination with other products or substances.

Determination of the suitability of any of COSMED's product(s) furnished hereunder for the use contemplated by Buyer is the sole risk and responsibility of Buyer, and COSMED has no responsibility in connection therewith. Buyer assumes all risks

and liabilities for loss, damage or injury to persons or property of Buyer or others arising out of the use or possession of COSMED's products.

The limited warranty as herein above set forth shall not be enlarged, diminished, modified or affected by, and no obligation or liability shall arise or grow out of, the renderings of technical advice or service by COSMED, its agents or employees in connection with Buyer's order or use of the product(s) furnished hereunder.

Return goods policy for warranty or non warranty repair

Goods shipped to COSMED for repair are subject to the following conditions:

1. Goods may only be returned after your receipt of a **Service Return Number (SRN)** from COSMED S.r.l.
2. Place your SRN report and Packing List outside the package.
3. Goods returned must be shipped with freight and insurance charges prepaid. **Collect shipments will not be accepted**.
4. The following list of goods are not eligible for return unless proven defective.
   - Special order items
   - Expendable products
   - Goods held over 30 days from COSMED's invoice date.
   - Used goods not in original shipping containers.
   - Goods which have been altered or abused in any way.
5. The following parts are not covered by warranty:
   - consumables
   - fragile glass or plastic parts
   - rechargeable batteries
   - damages due to use of the device not conforming to the indication reported in this manual

Repair Service Policy

Goods returned to seller for Non-Warranty repair will be subject to conditions 1, 2, 3, 4.

The returned goods need to re-enter COSMED together with the customs documents (Pro-forma Invoice and Customs Paper) as requested by the Italian law.

- The shipment has to be qualified as a Temporary Export.

- All the goods returned to COSMED without the customs papers will not be accepted.

For European Community members:

Pro-Forma invoice complete with:

- Number
- Description of the goods
- Quantity
- Serial Number
- Value in €
- Number of parcel
- Gross weight
- Net weight
- Reason for resent (i.e. Resent for repair)

In case you should send the system for repair please contact the nearest service centre or contact COSMED at the following address:

COSMED S.r.l.

Via dei Piani di Monte Savello 37
P.O. Box 3
00040 Pavona di Albano - Rome, Italy
tel. +39 (06) 9315492
fax +39 (06) 9314580
E-mail: customersupport@cosmed.it

For USA customers only please contact:

COSMED USA Inc

1808 North Halsted Street
Chicago, IL 60614 USA
Phone: +1 (312) 642-7222
Fax: +1 (312) 642 7212
email: usa.sales@cosmed.it

To ensure that you receive efficient technical assistance, please specify as precisely as possible the nature of the problem as it is specified on the assistance information form.

We advise you to save the original packaging. You may need it in case to ship the unit to a technical assistance centre.

Privacy Information

Dear Customer,

we inform you that your personal data are gathered and will be used by Cosmed Srl in conformity with the requirements of the Italian privacy law (Decreto Legislativo 196/2003). We believe it is important for you to know how we treat your personal data.

Personal data treatment and purposes

We request and process your personal data:

a. to place an order, register a product, request a service, answer a survey, enter a contest, correspond with us (all of the above, in the following: "service") and, if necessary, to supply the Competent Authorities with the required information;

b. in order to define your commercial profile;

c. in order to use your commercial profile for own marketing and advertising purposes;

d. for accounting purposes, including e-mailing of commercial invoices;

e. for providing your information to selected business partners (also abroad), in order to supply the service;

How your personal data are treated

Your personal data will be stored in electronic format, and protected at the best from destruction, loss (even accidental), not authorized accesses, not allowed treatment or use not in conformity with the purposes above listed.

The consent is optional, but...

If you deny the consent, we regret we cannot supply the service.

Holder of the treatment

The holder of the treatment is Cosmed Srl, Via dei Piani di Monte Savello 37, Pavona di Albano Laziale (RM). The responsible of the personal data treatment is indicated in the documentation stored by Cosmed Srl itself.

Customer rights

In accordance with art.7 of the Law, you can:

a. obtain confirmation of the existence of your personal data and their communication in intelligible form;

b. obtain:

- updating, correction or integration of your data;
- deletion or transformation in anonymous form of your personal data;

c. deny your consent to the treatment of your personal data;

These rights can be exercised directly requesting in writing to the holder of the treatment.

ATS 94 recommendations

Reference: “Standardization of Spirometry: 1994 Update” “American J. Respiratory Critical Care Medicine”, Vol. 152, 1107-1136; 1995.

ATS recommendations

Volume range:	8l (BTPS)
Flow range:	±14 l/sec
Volume accuracy:	±3% or < 50ml
Flow accuracy:	±5% or < 200ml/sec
Flowmeter resistance:	<1.5 cmH2O da 0 a 14 l/sec

Reproducibility: the 2 largest of 3 acceptable FEV1 and FVC values should be within 5% or 150 ml.

The end of test: no change in volume for 1 second with at least 6 seconds of collected volume.

Accumulation time: the maximum time allowed for volume accumulation during the VC manoeuvre should be at least 30 seconds and at least 15 seconds during the FVC.

The spirometer should be store at least 8 FVC maneuvres.

FEV1 should be calculated by using the “back extrapolation” method to detect the start of the test, extrapolated volume must not be higher then 5% FVC or 150ml.

The graphic resolution of the printed report must be as in the following:

Volume:	10 mm/l
Flow:	5 mm/l/sec
Time:	20 mm/sec
F/V ratio:	2:1

The total number of error (FVC e FEV1 >±3.5%, FEF25-75% >5.5%) during the measurement of the 24 standard waveforms must be lower than 4.

Predicted values

ERS93

Reference Adult:

Standardized Lung Function Testing: Official Statement of the European Respiratory Society, The European Respiratory Journal Volume 6, Supplement 16, March 1993.

Reference Paediatric:

Compilation of reference values for lung function measurements in children: Ph. H. Quanjer, J. Stocks, G.Polgar, M. Wise, J. Karlberg, G. Borsboom; ERJ 1989, 2, Supp.4,184s-261s.

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Reference Adult/ Paediatric:

Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Anging: J. Knudson, D. Lebowitz, J. Holdberg, B. Burrows; ARRD 1983; 127:725-734

Note: SD@FEV1/FVC e FEV1/VC da ERS93

ITS (White race)

Reference Adult/ Paediatric:

Intermountain Thoracic Society: Clinical Pulmonary Function Testing, second edition (1984) pp 101, 144

Note: SD@FEV1/FVC e FEV1/VC da ERS93

ITS (Black race)

Reference Adult/ Paediatric:

Intermountain Thoracic Society: Clinical Pulmonary Function Testing, second edition (1984) pp 101, 144

Note: SD@FEV1/FVC e FEV1/VC da ERS93

LAM

Reference Adult/ Paediatric:

A survey of ventilatory capacity in Chinese subjects in Hong Kong: Lam Kwok-Kwong, Pang Shing et Al. Annals of Human Biology, 1982, vol. 9, No. 5, 459-472.

Note: SD@FEV1/FVC e FEV1/VC da ERS93

Multicéntrico de Barcelona

Reference Adult/ Paediatric:

Spirometric reference values from a Mediterranean population: J. Roca, J. Sanchis, A. Agusti-Vidal, F. Segarra, D. Navajas. R. Rodriguez-Roisin, P. Casan, S. Sans. Bull. Eur. Physiopathol. Respir. 1986, 22, 217-224.

NHANES III

Reference Adult/ Paediatric:

Spirometric reference values from a sample of the general US population: John L. Hankinson, John. R. Odencrantz and Kathleen B. Fedan. Am J Respir Critr Care Med 1999, 159, 1798-187.

Automatic diagnosis (algorithm)

Reference: "Lung Function Testing: selection of reference values and interpretative strategies", A.R.R.D., 144/ 1991:1202-1218.

LLN=Pred-0.674*SD (ATS, 50° percentile)

LLN=Pred-1.647*SD (ERS, 95° percentile)

LLN=Pred*0.8 (80%Pred)

Message interpretation	Criterion
Normal Spirometry	FVC and FEV1/FVC > LLN
Obstructive abnormality (it may be physiological)	% Pred FEV1 >= 100
Obstructive abn.: mild	% Pred FEV1 < 100 and >= 70
Obstructive abn.: moderate	% Pred FEV1 < 70 and >= 60
Obstructive abn.: mod. severe	% Pred FEV1 < 60 and >= 50

Obstructive abn.: severe	% Pred FEV1 < 50 and >= 34
Obstructive abn.: very severe	% Pred FEV1 < 34
Restrictive abn.: mild	FVC<LLN and %Pred FVC>=70
Restrictive abn.: moderate	% Pred FVC < 70 and >= 60
Restrictive abn.: mod. severe	% Pred FVC < 60 and >= 50
Restrictive abn.: severe	% Pred FVC < 50 and >= 34
Restrictive abn.: very severe	% Pred FVC < 34

Quality Control Messages

Reference**:** Spirometry in the Lung Health Study: Methods and Quality Control, ARRD 1991; 143:1215-1223.

Message	Criterion
Start faster	VEXT >5% of the FVC and >150ml
Blast out harder	PEFT >120 msec
Avoid coughing	50% drop in the flow in first second
Blow out longer	FET100% <6 sec.
Blow out more air	flow >0.2l/s within 20 ml of FVC
Blow out harder	dPEF<10%
Take a deeper breath	dFVC<200ml and 5% best FVC
Blow out faster	dFEV1<200ml and 5% FEV1
That was a good test	No errors
FVC reproducible	diff. 2 max FVC within 0.2 l
FEV1 reproducible	diff. 2 max FEV1 within 0.2 l
PEF reproducible	diff. 2 max PEF within 10 %
MVV time too short	MVV time less than 12 sec

References

ATS '94: "Standardization of Spirometry: 1994 Update", American J. Respiratory Critical Care Medicine, Vol. 152, 1107-1136; 1995

ERS '93: "Standardized Lung Function Testing: Official Statement of the European Respiratory Society", The European Respiratory Journal Volume 6, Supplement 16, March "

"Standardization of Spirometry: 1987 Update", American Review of Respiratory Disease, Vol. 136, 1285-1289; 1987

Lung function", J.E. Cotes, Blackwell scientific publications

"Guidelines for Clinical Exercises Testing Laboratories", I.L. Pina, G.J. Balady, P. Hanson, A.J. Labovitz, D.W. Madonna, J. Myers. American Heart Association. 1995; 91, 912.

"Office spirometry", R.E. Hyatt - P.L. Enright, Lea & Febiger